

REMARKS

Applicants thank the Examiner for entering the Applicants' amendment filed on May 31, 2005. Applicants also thank the Examiner for the allowance of claims 16-21 and 41. In the present amendment, claims 38 and 42 have been amended to delete the term "human" and new claims 43 and 44 have been added. Support for the claim amendments and new claims can be found in the originally filed specification, for example, at least at page 4, lines 21-23 and page 5, lines 22-26, and the priority document at least at page 2, line 22 through page 3, line 2. *No new matter has been added.*

Accordingly, upon entry of the present amendment, claims 16-21, 38, and 40-44 will be pending. Any amendments to and/or cancellation of the claims should in no way be construed as acquiescence to any of the rejections and was done solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed or as previously pending in this or a separate application(s).

Claim Rejections – 35 USC §112, Second Paragraph

Claims 38, 40 and 42 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite on the ground that the metes and bounds of the terms "% identity" and "human" are not clear.

Applicants respectfully traverse this rejection. Regarding the term "human," claims 38 and 42 have been amended such that they no longer include the term "human," thereby, making this rejection moot with respect to the term "human."

Regarding the term "% identity," the final Office Action asserts that "[t]he term '% identity' is a relative term whose metes and bounds are not clear because one skilled in the art requires specific algorithms to calculate % identity." (Office Action at page 2). It appears that this rejection is in response to Applicants' amendment filed on May 31, 2005, in which the Applicants argued that the percentage identity between the claimed sequence and that disclosed in Waldmann *et al.* (J. Biol. Chem., 1997) was 83.5% and not 85.6%, as previously asserted by the Examiner (*See* Office Action mailed November 30, 2004). However, contrary to the Examiner's understanding, the Applicants were not asserting that the algorithm used in the Examiner's calculations was erroneous and the calculation of identity arrived at by the Applicants was correct.

Instead, Applicants were simply clarifying that the instant claims recite % *identity*, *i.e.*, “the extent to which two (nucleotide or amino acid) sequences are invariant,” as defined by the National Center for Biotechnology Information (*see* <http://www.ncbi.nlm.nih.gov>) and not % *similarity*, *i.e.*, “the extent to which nucleotide or protein sequences are related,” as also defined by the National Center for Biotechnology Information. Specifically, the % identity in both the alignment provided by the Examiner and that performed by the Applicants is 83.5% and is independent of the algorithm used. It is the % similarity, which is calculated based on both identical and conservative amino acid changes, which appears to be higher. Therefore, the metes and bounds of the term “% identity” are not ambiguous or dependent on a particular algorithm. Regardless of which algorithm is used, it would be clear to one of ordinary skill in the art that the instant claims encompass sequences which show at least 85% identity to the amino acid sequence set forth in SEQ ID NO:2.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claim Rejections – 35 USC §112, First Paragraph

Claims 38, 40 and 42 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the Written Description requirement on the ground that “one skilled in the art cannot envision all the various species of peptide which is ‘human’ and ‘85% identity with SEQ ID NO:2 with the function of being inhibited by amelioride.” (Office Action at page 3).

Applicants respectfully traverse this rejection as they pertain to the amended claims. Applicants believe that the Examiner has applied an incorrect standard for Written Description to the instant case. For example, as the Federal Circuit explained in *Lizardtech v. Earth Resource Mapping, Inc.* 424 F. 3d 1336 (Fed. Cir. 2005)

[a] claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. *See* Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000). That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. In *re* GPAC Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995).

Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation (emphasis added)

Applying the aforementioned legal precedent to the instant case, Applicants submit that Written Description does not require that a specification disclose each and every embodiment encompassed by a claim, but that the specification provides sufficient disclosure for one skilled in the art at the time of the invention to make and use the embodiments encompassed by the claims without undue experimentation. Accordingly, based on the teachings of the specification as filed coupled with the knowledge in the art at the time of the invention, one of ordinary skill in the art would have readily been able to both make and/or identify species of peptides that have at least 85% identity to the amino acid sequence set forth in SEQ ID NO:2 and determine whether they have the recited activity. The specification as filed provides several assays for identifying those sequences having at least 85% identity as well as assays to determine those that have the functional characteristics recited in the claims. See, for example, the specification as filed at page 11, lines 7-29, which provides an assay which may be used for identifying those peptides that displays a biphasic current when activated by an extracellular proton concentration which is below physiological pH, and where the slow component of the biphasic current is inhibited by amiloride. Accordingly, contrary to the Examiner's assertions, one of ordinary skill in the art would have readily been able to identify species of SEQ ID NO:2 that have at least 85% amino acid sequence identity to SEQ ID NO:2 and the recited functional characteristics.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim Rejections under 35 U.S.C. §102(e)

The rejection of claims 38-40 under 35 U.S.C. §102(e) as being anticipated by DeWeille *et al.* (U.S. 6,287,859) (hereinafter "*DeWeille*") and Renard *et al.* (US 2002/173000) (hereinafter "*Renard*") is maintained on the ground that the claimed subject matter is not entitled to the earliest priority.

Applicants respectfully traverse this rejection. It is well ingrained in the law that lack of literal support is not sufficient ground to support a rejection under 35 U.S.C. §112. For example, as noted by the Court in *In re Wertheim* (541 F.2d 257, 262)

[i]f lack of literal support alone were enough to support a rejection under §112, then the statement of *In re Lukach*, supra, 58 CCPA at 1235, 442 F.2d at 969, 169 USPQ at 796, that '*the invention claimed does not have to be described in ipso verbis in order to satisfy the description requirement of §112,*' is empty verbiage (*emphasis added*)

Applying the above-set forth legal precedent to the instant case, Applicants submit that the priority document provides more than adequate disclosure to support claims directed to variants of SEQ ID NO:2, *i.e.*, having at least 85% identity to the sequence of SEQ ID NO:2, and the recited functional characteristics. For example, the priority document encompasses peptides that are encoded by nucleic acid sequences which hybridize under highly stringent conditions to the nucleic acid sequence that encodes the peptide of SEQ ID NO:2, and which have the recited functional characteristics. See, *e.g.*, page 2, line 22 through page 3, line 2; page 5, lines 61-21. Accordingly, Applicants submit that it would be clear to one of ordinary skill in the art that such peptides would inherently include those peptides that have a high percentage of sequence identity to the amino acid sequence of SEQ ID NO:2, *e.g.*, peptides having at least 85% identity to the amino acid sequence set forth in SEQ ID NO:2 and the recited functional activity.

In view of the foregoing, Applicants request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080 under Order No. PCI-017USRCE from which the undersigned is authorized to draw.

Dated: September 26, 2006

Respectfully submitted,

By 

Cynthia L. Kanik, Ph.D.

Registration No.: 37,320

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)

Attorney/Agent For Applicant